UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,351	02/21/2007	Georg Gradl	F-9052	7191

28107 7590 10/14/2009

JORDAN AND HAMBURG LLP
122 EAST 42ND STREET
SUITE 4000
NEW YORK, NY 10168

EXAMINER	
BOLES, SAMEH RAAFAT	
ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
10/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,351	GRADL, GEORG	
	Examiner	Art Unit	
	SAMEH BOLES	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 32-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 32-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/17/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

According to the Amendment filed on July 27, 2009, claims 1 and 53 have been amended, claims 2-31 are cancelled; and claims 1, 32-69 are pending and have been examined in this office action.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

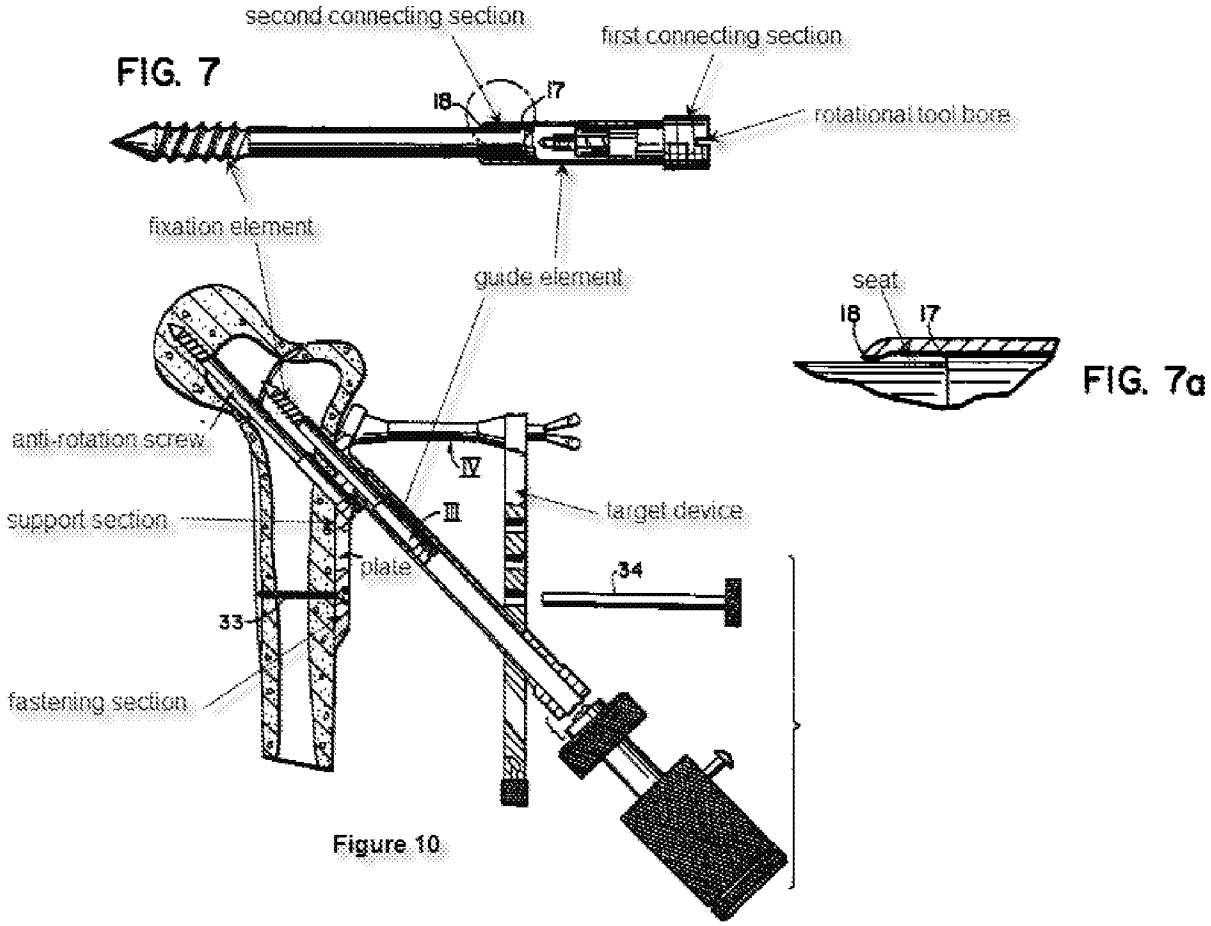
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 34, 38-40, 46- 58, 66, 68 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Gotfried (US. Pat. No. 5,429,641).

Gotfried discloses a system for minimally invasive treatment of a fracture of a bone such as femoral fracture (see modified Figure 10 below), comprising an osteosynthetic plate (I) including a support section positionable with a support surface against said bone adjacent to the fracture and a fastening section for fixing said osteosynthetic plate to said bone; a fixation element (see modified Figure 10 below) for fixing in a fragment of said bone that was dislodged by the fracture and comprising a shaft portion (10, Fig. 3), wherein said fixation element includes a screw head with a self-cutting thread (11); and a guide element (Fig. 6) including a first connecting section (15, Fig. 6) via which said guide element is fastenable to said osteosynthetic plate (see modified Figure 10 below) and a second connecting section for guiding said fixation element (see modified Figure 10 below), wherein said second connecting section of

said guide element providing an inner bore (may be considered as a seat) (see modified Figure 7a below) in which a shaft of said fixation element is slidably and tightly received (col. 4, lines 59-60), such that the shaft portion of said fixation element is free from tilting therein and moveable axially with respect thereto; said guide element axially includes a rotational tool bore (16, Fig. 16) for receiving a rotational tool; said support section of said osteosynthetic plate has having at least first and second recesses (5, Fig. 2), said fixation element and said guide element being insertable into said bone through said first recess (see modified Figure 10 below), wherein said first recess in said support section and said guide element are configured such that a longitudinal axis of said guide element and a tangent on a side of said osteosynthetic plate facing said bone are at an angle; a fastening structure for holding said guide element axially fast in both directions after placement into said osteosynthetic plate, wherein said fastening structure includes a male thread (15, Fig. 6) provided on said first connecting section of said guide element and a female thread that provided in said first recess engageable with the male thread (abstract); said shaft and said second connecting section are configured in a circular shape such that an axial rotation of said fixation element is permitted in said guide element, wherein said shaft of said fixation element includes catch surfaces that hold said fixation element rotationally fast in said seat; a rotation inhibiting structure for preventing rotation of the bone fragment dislodged by the fracture, wherein: said support section of said osteosynthetic plate includes at least a second recess; and said rotation inhibiting structure for preventing rotation includes a second fixation element (may be considered as an anti-rotation screw) (II, Fig. 10) that has a head and that can

be placed into the dislodged fragment of said bone through said at least a second recess in said support section, wherein said at least a second recess has a female thread and said anti-rotation screw has a corresponding male thread (15, Fig. 6) at the head; and a target device (see modified Figure 10 below) that is detachable with said osteosynthetic plate via at least one clamping section, wherein said target device includes target bores that are aligned with the recesses in the osteosynthetic plate when said target device is connected to said osteosynthetic plate.



Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 32, 33, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US. Pat. No. 5,429,641).

Gotfried discloses the claimed invention except that the first recess in said support section and said guide element are configured such that a longitudinal axis of said guide element and a tangent on a side of said osteosynthetic plate facing said bone are at an angle of between 50° and 70° or at an angle of between 55° and 65°.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the angle between the guide element and the osteosynthetic plate is between 50° and 70° or at an angle of between 55° and 65°, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

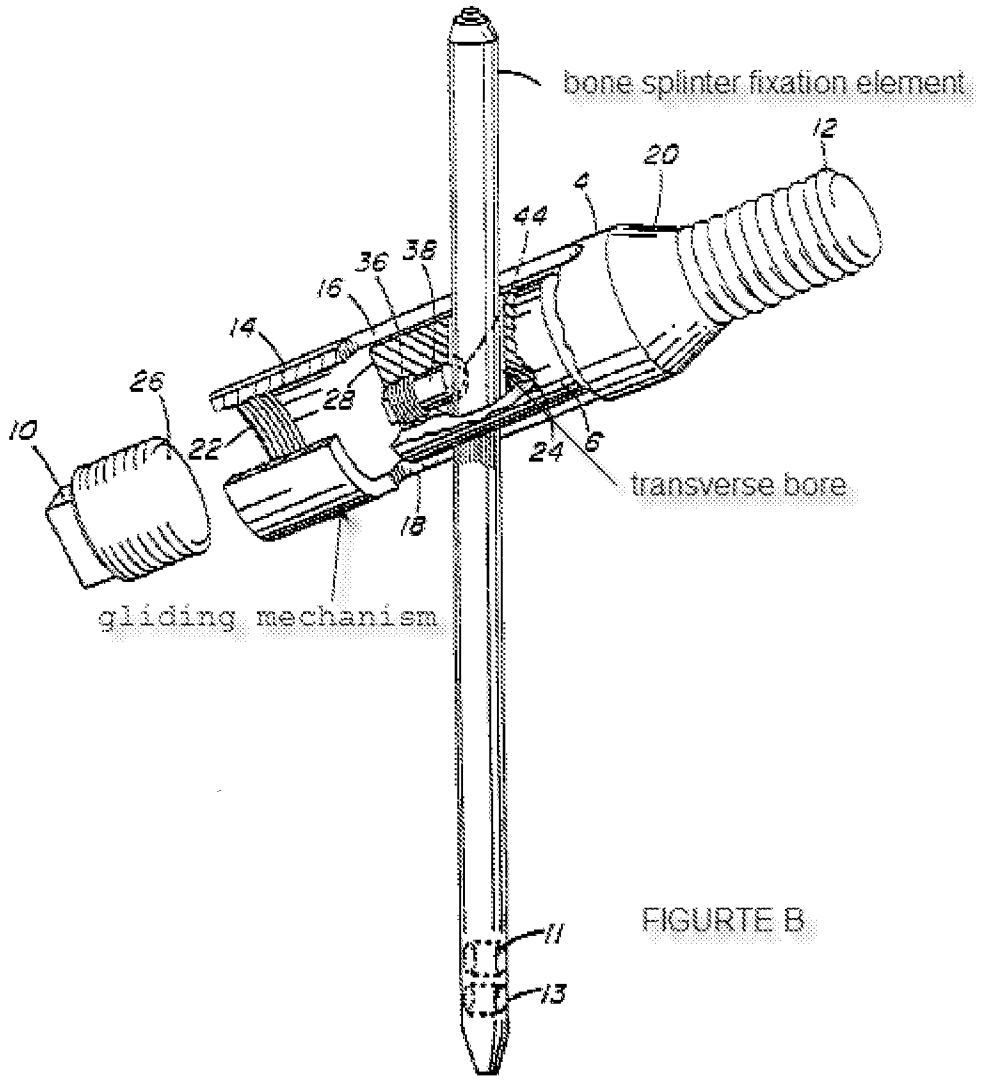
5. Claims 35, 41- 44, 61- 64 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US. Pat. No. 5,429,641) in view of Nelson (US. Pat. No. 6,562,042 B2).

Gotfried discloses the claimed invention except an alignment structure operable to adjust and/or control a rotational position of said guide element relative to said osteosynthetic plate comprising: a bone splinter fixation element fixable in or to said

guide element, wherein: said guide element includes a transverse bore; and said bone splinter fixation element fixable in said transverse bore.

Nelson discloses a system for treating a bone fracture comprising an alignment structure (see Figure B below) operable to adjust and/or control a rotational position of a gliding mechanism (may be considered as a guide element) comprising: a bone splinter fixation element fixable in said guide element, wherein: said gliding mechanism includes a transverse bore; and said bone splinter fixation element fixable in said transverse bore.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the system for treatment of a fracture of a bone of Gotfried with an alignment structure in view of Nelson for effectively controlling the rotational position of said guide element inside bone.



FIGURTE B

Gotfried in view of Nelson disclose the claimed invention except that said longitudinal bone splinter fixation element and a longitudinal axis of said guide element create an angle of between 60 and 100° or an angle of between 70° and 90°.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the angle between the guide element and the bone splinter fixation element is between 60 and 100° or an angle of between 70° and 90°,

since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

6. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US. Pat. No. 5,429,641) in view of Lower (US. Pat. No. 4,612,920).

Gotfried discloses the claimed invention except that said fastening structure includes a groove provided in said first recess of said support section and a stop which is disposed in said groove for limiting a rotational movement of said guide element.

Lower discloses a system for treating a bone fracture comprising a fastening structure (see Figure C below) for holding a guide element axially fast in both directions after placement into a osteosynthetic plate, wherein said fastening structure includes a groove provided in said first recess of said support section and a stop which is disposed in said groove for limiting a rotational movement of said guide element.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the fastening structure of Gotfried with a groove and a stop in view of Lower for effectively limiting the rotational movement of said guide element.

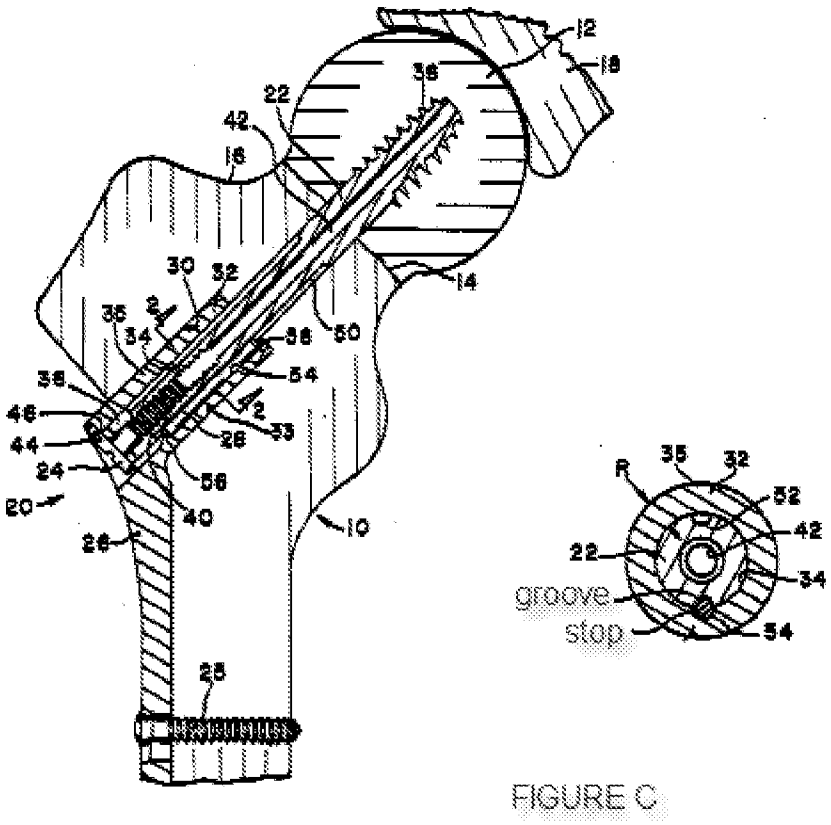


FIGURE C

7. Claims 45 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US. Pat. No. 5,429,641) in view of Nelson (US. Pat. No. 6,562,042 B2) and further in view of Lee et al. (US. Pat. No. 3,939,498).

Gotfried in view of Nelson disclose the claimed invention except that said bone splinter fixation element includes a screw that has a pressure body with claws.

Lee et al disclose a fixation system comprising of a bone fixation element includes a screw that has a pressure body with claws (see Figure D below).

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the bone splinter fixation element of Gotfried in view

of Nelson with a pressure body with claws further in view of Lee et al for effectively securing the screw head of the bone splinter fixation element to bone.

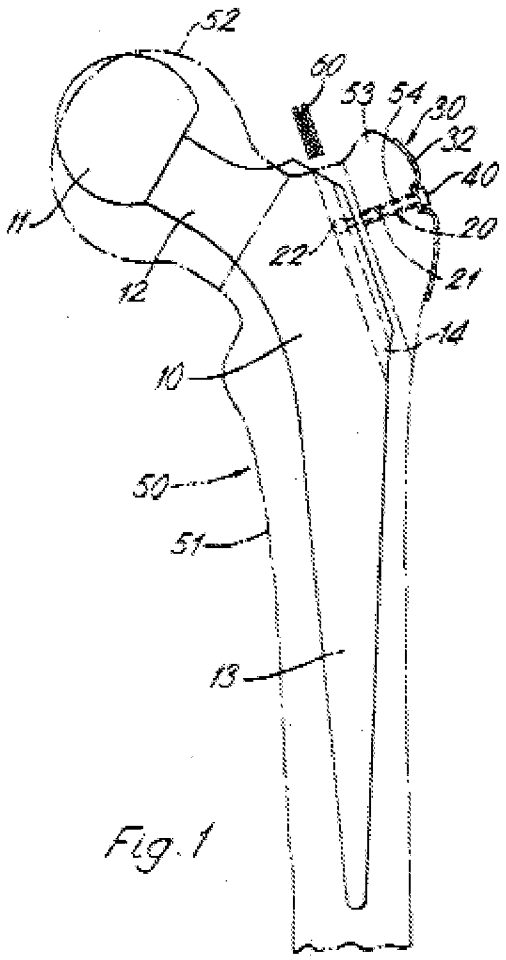


Fig. 1

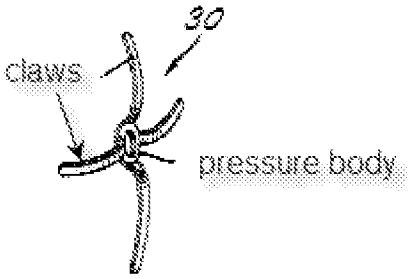


FIGURE D

Response to Arguments

Applicant's arguments filed July 27, 2009 have been fully considered but they are not persuasive.

Applicant argues that Gotfried fails to teach or suggest Applicant's recited "guide element," and thus is unable to provide the positional arrangement, positional accuracy and adjustment associated with guiding and fixation element.

Examiner respectfully disagrees, since it is noted that the features upon which applicant relies in his argument regarding the positional arrangement, positional accuracy and adjustment associated with guiding and fixation element, are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Also, applicant's structural limitations as claimed reads on Gotfried's invention.

Applicant argues that Gotfried fails to teach or suggest Applicant's guide element and its "second connecting section providing a seat in which said shaft portion of said fixation element is free from tilting therein and moveable axially with respect thereto".

Examiner respectfully disagrees, since Gotfried teaches a guide element (Fig. 6) including a first connecting section (15, Fig. 6) via which said guide element is fastenable to said osteosynthetic plate (see modified Figure 10 above) and a second connecting section for guiding said fixation element (see modified Figure 10 above), wherein said second connecting section of said guide element providing an inner bore (may be considered as a seat) (see modified Figure 7a above) in which a shaft of said fixation element is slidably and tightly received (col. 4, lines 59-60), therefore the fixation element is free from tilting therein and moveable axially with respect thereto.

Also, Applicant argues that Gotfried fails to teach or suggest Applicant's recited "anti-rotation screw for substantially preventing rotation of the bone fragment and

comprising a head portion for insertion through said second recess of said support section and into said dislodged bone fragment said head portion and said second recess being threaded for mating engagement therebetween."

Examiner respectfully disagrees, since Gotfried teaches a second fixation element (may be considered as an anti-rotation screw) (II, Fig. 10) that has a head and that can be placed into the dislodged fragment of said bone through said at least a second recess in said support section (see modified Fig. 10 above), wherein said at least a second recess has a female thread (col. 4, lines 42-44) and said anti-rotation screw has a corresponding male thread (15, Fig. 6) at the head.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMEH BOLES whose telephone number is (571)270-5537. The examiner can normally be reached on Monday - Friday 7:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAMEH BOLES/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775